

## **REMARKS**

Claims 64-70 were pending in the present application. Applicants have added new claim 75.

Support for new claim 75 may be found *inter alia* on page 4, paragraph [0040], on pages 6-7, paragraphs [0064]-[0078], on page 18, paragraph [0204] and on page 38, paragraph [0381] of U.S. Patent Application Publication US 2005/0020810.

Applicants believe that no new matter is added by this amendment.

Upon entry of this amendment, claims 64-70 and 75 will be pending.

Entry of the foregoing amendments and consideration of these remarks are respectfully requested.

### ***Claim Rejections under 35 U.S.C. § 102***

On page 2 of the November 1, 2006 Office Action, the Examiner noted that the species elected by the applicants in their May 27, 2005 reply (i.e. Ac-Pro-His-Ser-Cys(Ac)-Asn-Dox) had been searched and found free of the prior art. Accordingly, the Examiner elected a new species (i.e. Ac-Pro-His-Ser-Cys-Asn-NH<sub>2</sub>), allegedly from amongst those encompassed by the instant claims.

The Examiner rejected claim 64 under 35 U.S.C. § 102(b) as allegedly anticipated by Livant et al, Cancer Research, 2000, Vol. 60, pp 309-320 ("Livant") or by U.S. Patent No. 6,001,965 issued Livant on December 14, 1999 ("the '965 patent").

The Examiner alleged that both references teach Formula V, Ac-Pro-His-Ser-Cys-Asn-NH<sub>2</sub> wherein s is 0, r is 0, R<sup>30</sup> is Ac, X<sup>2</sup> is Pro, X<sup>3</sup> is His, X<sup>4</sup> is Ser, X<sup>5</sup> is Cys, y is 0, n is 1, R<sup>13</sup> is H, X<sup>6</sup> is Asn, m is 1, R<sup>4</sup> is H and R<sup>31</sup> is H, citing to the abstract of Livant and claims 1-3 of the '965 patent.

The legal standard under 35 U.S.C. § 102 states that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. See *e.g. Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, under the anticipation standard when a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art. See *e.g. Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001).

Applicants respectfully disagree with the Examiner's rejection and point out to the Examiner that claim 64 does not encompass the species elected by the Examiner nor the disclosures of the cited references. Claim 64 recites in part "that at least one of R<sup>30</sup>, R<sup>31</sup> or R<sup>32</sup> is present and is a therapeutic agent." In the compounds disclosed in Livant, a structure corresponding to "R<sup>32</sup>" is not present and the structures corresponding to "R<sup>30</sup>", and "R<sup>31</sup>" are not therapeutic agents. In the '965 patent, none of the compounds disclosed have structures corresponding to "R<sup>30</sup>", "R<sup>31</sup>" or "R<sup>32</sup>" that are therapeutic agents. Applicants also note that in the species elected by the Examiner, "R<sup>32</sup>" is not present and neither "R<sup>30</sup>", nor "R<sup>31</sup>" are therapeutic agents. Therefore, neither Livant nor the '965 patent disclose each and every element of claim 64. Since Livant and the '965 patent each do not disclose every element of claim 64, they do not anticipate Claim 64 or any of the claims which depend on claim 64. Accordingly, the Examiner is requested to reconsider and withdraw the rejection of claim 64 under 35 U.S.C. 102(b) as anticipated by Livant or by the '965 patent.

### ***Double Patenting***

The Examiner has provisionally rejected claims 64-70 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 5, 19-20, 22-42, 55-56 and 58-59 of co-pending Application No. 10/723,144 ("the '144 application"). Specifically, the Examiner contends that the instantly claimed invention and the invention claimed in the '144 application are both drawn to a genus of compounds which contain overlapping subject matter. The Examiner further contends that the instantly claimed broad formula (V) of the instant application encompasses and/or is encompassed by the claimed broad formula (I) of the '144 application. Applicants respectfully disagree.

The legal standard for an obviousness-type double patenting rejection requires a comparison of what is *claimed* in the earlier patent, not what was disclosed in the specification of the earlier patent. See *e.g.*, *General Foods, Inc. v. Studiengesellschaft Köhle mbH*, 972 F.2d 1272, 1280-81 (Fed. Cir. 1992). Although the specification may be used to determine the meaning of terms used in the claims, the specification may not be used as prior art. See *e.g.*, *In re Vogel*, 422 F.2d 438 (C.C.P.A. 1970).

Applicants respectfully submit that claims 1, 5, 19-20, 22-42, 55-56 and 58-59 of the '144 application, which are directed to compounds of formula (I), do not render obvious the claimed compounds of formula (V) of the subject application. In particular, Applicants submit that the compounds of formula (V), in which at least one of "R<sup>30</sup>", "R<sup>31</sup>" or

"R<sup>32</sup>" is present and is a therapeutic agent, are not obvious over the compounds of formula (I) of the '144 application because there is no teaching or suggestion in the claims of the '144 application of conjugation to a therapeutic agent. Moreover, claims 1, 5, 19-20, 22-42, 55-56 and 58-59 of the '144 application do not teach or suggest a compound within the scope of the presently claimed invention. The present claims are directed to compounds which are conjugated to a therapeutic agent whereas the claims of the '144 application recite compounds which are not conjugated to a therapeutic agent.

Thus, Applicants respectfully submit that claims 64-70 as well as new claim 75 are patentably distinct from claims 1, 5, 19-20, 22-42, 55-56 and 58-59 of the '144 application.

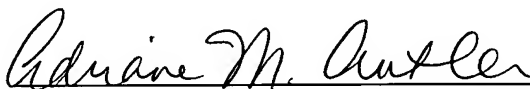
For the above reasons, Applicants respectfully request withdrawal of the double patenting rejection.

#### **CONCLUSION**

Applicants respectfully request that the present amendments and remarks be entered and made of record in the instant application. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

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